

## **REMARKS**

Applicants wish to thank the Examiner for reviewing the present patent application and for entering the prior submission under 37 CFR §1.114. Support for the amendments may be found, among other places on pages 8, 33, 34 and/or 42 of the specification as originally filed. Thus, no new matter has been added.

### **I. Rejection Under 35 USC §103**

The Examiner has again rejected claims 1, 2, 5-6, and 9 under 35 USC §103 as being unpatentable over Granger et al., U.S. Patent No. 5,723,139 (hereinafter, '139) and Gorbach (WO 98/56373) (hereinafter, '373) in view of Liu et al., U.S. Patent No. 5,976,555 (hereinafter, '555) and Soares et al., U.S. Patent No. 5,941,116 (hereinafter, '116). In the rejection, the Examiner again mentions, in summary, that the '139 reference discloses a skin conditioning composition comprising retinal or retinyl ester in an amount from about 0.001% to about 10% in combination with a retinoid booster, polycyclic triterpene carboxylic acid and glycyrrhetic acid in an amount of from about 0.0001% to about 50%. The Examiner again mentions that the reference suggests that the combination of retinal or a retinyl ester with a polycyclic triterpene carboxylic acid results in synergistic inhibition of keratinocyte differentiation, and that retinoid boosters may be employed. Moreover, the Examiner continues to note and correctly acknowledges that the '139 reference fails to disclose a composition with phytoestrogens and a dual compartment system. The Examiner continues and states that the '373 reference teaches that phytoestrogens such as genistein, daidzein, glycitin, equol, and formononetin are useful to treating wrinkles and aging skin. The Examiner continues and states that the '555 reference teaches that retinoids such as

retinal and retinyl ester in skin care compositions are unstable due to oxidation or isomerization to non-efficacious chemical forms, and further teaches that several stable compositions for skin care can be supplied in two bottles separating retinoids from cosmetic ingredients. Finally, the Examiner, again, relies on the '116 reference and mentions that the same describes skin compositions in separate containers.

In view of the above, the Examiner continues to conclude that one of ordinary skill in the art would have found it obvious at the time the invention was made to employ two compartments, the first one for storing retinoids and the second one for storing retinoid booster and a phytoestrogen to keep retinoids from reacting with its booster in order to preserve the stability of retinoids and avoid chemical degradation prior to use. Thus, the Examiner maintains that the rejection made under 35 USC §103 is warranted.

Notwithstanding the Examiner's apparent position to the contrary, it is the Applicants' position, again, that the presently claimed invention is patentably distinguishable from the above-described for at least the following reasons.

The present invention, as set forth in independent claim 1, as now presented, is directed to a stable skin care product containing a first composition comprising about 0.001% to about 10% of a retinoid; and a second composition comprising about 0.0001% to about 50% of at least one retinoid booster selected from the group consisting of arachidic acid, myristic acid, amsacrine, carbenoxolone, glycyrrhetic acid, phosphatidyl ethanolamine, sphingomyelin, phosphatidylcholine, and mixtures thereof, and from about 0.001% to about 10% of at least one phytoestrogen selected from the group consisting of genistein, diadzein, glycitin, biochanin A, formononetin, equol, and mixtures thereof, a first compartment for storing the first composition and a second compartment for storing the second composition whereby the first and second

compartments are joined together. Independent claim 1 is further defined in that the retinoid booster potentiates the action of the retinoid and inhibits degradation of retinoic acid, the first and second composition are retained separately and only come in contact after being applied simultaneously or consecutively, and the phytoestrogen is one which synergistically interacts with the retinoid.

The invention of independent claim 1 is also characterized in that the stable skin care product is defined to be one suitable to treat acne, wrinkles, psoriasis, age spots or discoloration on skin.

The invention of claim 1 is further defined by the dependent claims which claim, among other things, that two retinoid boosters may be used in an amount from about 0.0001% to about 50% in the second composition, that the retinoid boosters provide synergistic inhibition to transglutaminase, and that about 1 to about 5 ml of each composition should be used.

The invention of independent claim 5, as now presented, is directed to a stable skin care product containing a first composition and a second composition wherein the first composition comprises from about 0.001% to about 10% of a retinoid to provide a first benefit, and the second composition comprising from about 0.0001% to about 50% of at least one retinoid booster selected from the group consisting of vanillin, arachidic acid, linoleic acid, myristic acid, amsacrine, carbenoxolone, glycyrrhetic acid, phosphatidyl ethanolamine, sphingomyelin, phosphatidylcholine, and mixtures thereof; and about 0.001% to about 10% of at least one phytoestrogen selected from the group consisting of genistein, diadzein, glycitin, biochanin A, formononetin, equol, and mixtures thereof, the booster and phytoestrogen boosting the first benefit; a first compartment for storing the first composition; and a second compartment for storing the

second composition, the first and second compartments being joined together. Moreover, the invention of independent claim 5 is further defined in that the retinoid booster potentiates the action of the retinoid and inhibits degradation of retinoic acid, the first and second composition are retained separately and only come in contact after being applied simultaneously or consecutively, and the phytoestrogen is one which synergistically interacts with the retinoid.

The invention of independent claim 5 is also characterized in that the stable skin care product is now defined to be one suitable to treat acne, wrinkles, psoriasis, age spots or discoloration on the skin.

The invention of claim 5 is further defined by the dependent claims which claim, among other things, that the second composition can have at least two retinoid boosters in an amount of from about 0.0001% to about 50%, that the retinoid booster may be selected from the group consisting of glycyrrhetic acid, phosphatidylcholine, and mixtures thereof, that the retinoid boosters provide synergistic inhibition to transglutaminase and that about 1 to about 5 ml of each composition should be used.

In contrast, and as already made of record on numerous occasions, the '139 reference is merely directed to a skin care composition having a polycyclic triterpene carboxylic acid and a retinoid. The '139 reference does not teach or suggest, even remotely, the use of the claimed phytoestrogens. Moreover, the '139 reference does not teach or suggest the storage of a first composition comprising retinoid, and a second composition comprising retinoid booster and phytoestrogens in a separate compartment that is joined with a compartment holding the first composition. In an attempt to cure the vast deficiencies of the primary reference, the Examiner relies on the '373 reference. The '373 reference, however, merely describes compositions that

have isoflavonoids to prevent aging and wrinkling of skin. The '555 reference, again, discloses a skin care composition having an oil-in-water emulsion base containing retinoids and possessing good physical and chemical stability. Again, it is reported in the '555 reference that the use of retinoids in topical compositions are unstable and can either oxidize or isomerize to non-efficacious chemical forms resulting in an amount of retinoid which is so low it is unacceptable to provide a benefit. As already made of record, attempts made to stabilize the retinoid in the '555 reference require a complex oil-in-water emulsion system for stabilization wherein the stabilizing system is one which requires, for example, oil-soluble antioxidants, chelating agents, or chelating agents and oil soluble antioxidants, or chelating agents and an antioxidant present in each of the oil and water phases of the emulsion. There is no teaching whatsoever in the '555 reference or in any combination of references relied on by the Examiner that even remotely suggests the combination of specific retinoids with specific boosters and phytoestrogens as claimed in the present invention whereby the booster potentiates the action of the retinoid and inhibits degradation of retinoic acid.

The two component system as claimed in this invention, as well as the two preferred boosters as claimed in this invention are not even remotely suggested by the '555 reference which, again, employs a complicated oil-in-water emulsion system to stabilize certain retinoids. Finally, and again, the '116 reference teaches away from the presently claimed invention. For reasons already made of record, the '116 reference merely describes a method for a skin treatment regime wherein a first and second composition are stored in separate containers and only connected to each other to remind the consumer to use the compositions in tandem and to facilitate in one sale all necessary elements of a suggested regime. Thus, the '116 reference clearly teaches away from the present invention and cures none of the vast deficiencies of the primary reference since it discloses two separate containers for separating two different skin

actives for two different benefits. Moreover, and again, the reference fails to even remotely teach, suggest or disclose the need to separate phytoestrogens from retinoids.

The present invention, again, is directed to two separate compositions with one intended to boost the benefit of the other. According to the present invention, the two compositions are intended to be applied simultaneously or consecutively, but are kept separately for stability reasons. The presently claimed invention clearly conveys that the specified retinoids and the phytoestrogens, although separated into two compartments, are there for the same benefit. The first composition provides a benefit to the skin while the second composition works to boost or enhance the effect of the first composition. Again, the '116 reference teaches away from the present invention and fails to provide any suggestion for the particular way the compositions of the present invention are stored separately.

Finally, the usage amounts and inhibition to transglutaminase is not suggested in the references relied on by the Examiner.

Again, the storage of the compositions in separate containers as set forth in the presently claimed invention is novel and unobvious. None of the references relied on by the Examiner, even remotely, teach all of the important and critical limitations set forth in the presently claimed invention as now presented. Since the Examiner has not established a *prima facie* case of obviousness as required under 35 USC §103, Applicants request that the obviousness rejection be withdrawn and rendered moot.

## II. Rejection Under 35 USC §103

The Examiner has again rejected claims 1, 2, 5, 6 and 9-10 under 35 USC §103 as being unpatentable over Granger et al., U.S. Patent No. 5,723,139 (hereinafter, '139), Gorbach, WO 98/56373 (hereinafter, '373), and Maybeck, FR 2 777 179 (hereinafter, '179) in view of Liu et al., U.S. Patent No. 5,976,555 (hereinafter, '555) and Soares et al., U.S. Patent No. 5,914,116 (hereinafter, '116).

The Examiner continues to mention that the '139 and '373 references are relied on for the reasons mentioned above and the '179 reference is relied on for mentioning skin care compositions with retinoid. The Examiner further mentions that the '139 reference does not describe a product with a first composition having a retinoid and a second composition comprising retinoid boosters and phytoestrogens in separate compartments.

Again, for the reasons already made of record, the '139 reference is directed to skin care compositions with polycyclic triterpene carboxylic acid and a retinoid. The '139 reference does not, even remotely, teach or suggest the claimed phytoestrogens. Moreover, the '139 reference does not teach or suggest the storage of a first composition comprising retinoid and a second composition comprising retinoid booster and phytoestrogens in a separate compartment whereby the two compartments are joined together. Also, the reference does not suggest amounts of use or the inhibition of transglutaminase as claimed in the present amendments.

As made of record, the '373 reference is merely directed to compositions with isoflavonoids. Simply because the '179 reference appears to disclose the phosphatidylcholine and glycyrrhetic acid somewhere in its disclosure clearly does not

make it obvious for one of ordinary skill in the art to combine these materials with retinoids and with retinoid boosters in a dual compartment package and to derive the present invention. The Examiner, again, cannot pick and choose elements from numerous references without there being a reason to combine the same. Furthermore, and as already made of record, the '555 reference is merely directed to the use of a complex oil-in-water emulsion comprising a specifically defined stabilizing system to stabilize certain retinoids. It has nothing to do with a dual compartment system as claimed in the present invention. Finally the '116 reference is directed to a treatment regime for skin that employs two different compositions that are to be used for two different benefits. The two different compositions have two different skin actives and they are stored in two separate containers. Again, the present invention is directed to two separate compositions with one intended to boost the other. As presented, the booster is present to potentiate the action of the retinoid and inhibit degradation of retinoic acid.

Such an arrangement of compositions allows for effective treatment of skin characteristics, and particularly, acne, wrinkles, age spots, and/or discoloration on the skin.

Based on the above, it is, again, clear that all the important and critical limitations set forth in the presently claimed invention are not found in the combination of references relied on by the Examiner. In view of this, Applicants respectfully submit, again, that a *prima facie* case of obviousness has not been established and the rejection made under 35 USC §103 should be withdrawn and rendered moot.



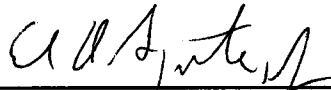
III. Rejection Under the Judicially Created doctrine of Obviousness-type  
Double Patenting

In an attempt to expedite the prosecution of this application, Applicants hereby submit the Terminal Disclaimer over U.S. Patent No. 6,565,864. Thus, it is requested that the obviousness-type double patenting rejection of claims 1-2, 5-6 and 9-10 be withdrawn in view of such submission.

Applicants also submit that the pending claims are now ready for allowance. Applicants welcome suggestions from the Examiner so that prosecution of this application may be expedited and so this application can pass to issue.

In the event the Examiner has any questions concerning the present patent application, the Examiner is kindly invited to contact the undersigned at his or her earliest convenience.

Respectfully submitted,



Edward A. Squillante, Jr.  
Registration No. 38,319  
Attorney for Applicant(s)

EAS/pod  
(201) 894-2925